THE COMPREHENSIVE ADDICTION RESOURCES EMERGENCY (CARE) ACT
Section-By-Section

Section 1: Short Title
Identifies the Act as the Comprehensive Addiction Resources Emergency Act of 2018.

Section 2: Purpose
States that the purpose of the Act is to provide emergency assistance to States, territories, Tribal nations, and local areas that are disproportionately affected by the opioid epidemic and to make financial assistance available to provide for the development, organization, coordination, and operation of systems for the delivery of services to individuals with substance use disorder and their families.

Section 3: Amendment to the Public Health Service Act
This section amends the Public Health Service Act to add a new title, "Substance Use and Opioid Health Resources."

SUBTITLE A (Grants to Local Areas)

SECTION 3401(a):
This section establishes a program, administered by the Secretary of Health and Human Services in coordination with the Director of the Office of National Drug Control Policy, to award grants to local areas for the purpose of addressing substance use within those areas.

SECTION 3401(b):
This section establishes eligibility criteria for the grants to be awarded on the basis of formulas. Eligible localities are (1) counties and independent cities with a rate of drug overdose deaths per 100,000 people not less than the rate of such deaths for the county at the 67th percentile of all counties; or (2) counties and independent cities that can demonstrate that the number of drug overdose deaths during the most recent three-year period was not less than the number of deaths for the county that ranked at the 90th percentile of all counties. Together, these criteria make the one-third of U.S. counties with the highest drug overdose mortality rates and the top 10 percent of U.S. counties with the highest overall numbers of drug overdose deaths eligible for formula funding. Cities located within eligible counties are also eligible to receive grant funding.

This section also requires that any eligible county that is contiguous to one or more other eligible counties form a group of counties that shall be considered as a single eligible county for the purposes of a grant, meaning the group of counties shall submit one grant application and form a joint planning council (as required under section 3402). Groups of counties must also establish an administrative mechanism to allocate funds and services under the grant based on the number of drug overdoses in each of the counties, the severity of the need for services, and the health and support service personnel needs of each county.

This section further stipulates that any city that is within an eligible county or any county within a group of contiguous counties shall be eligible to receive its own grant—independent from the

group of contiguous counties—if it has a population of at least 50,000 residents, submits its own application, and establishes its own planning council.

This section also allows any such city, county, or group of counties that does not meet the population threshold to apply to the Secretary for a waiver of the requirement that they form part of a group of contiguous counties if they can demonstrate that the needs of their population are distinct, that addressing substance use in the area would be best served by the formation of an independent planning council, and that the entity has the capacity to administer grant funding.

This section also states that cities or counties qualifying to receive their own grants are entitled to receive at least the amount of funding they would have qualified for on their own, based on their number of drug overdose deaths.

This section directs the Secretary to determine eligible local political subdivisions in the cases of States that do not have a local county system of governments and to establish eligibility criteria for cities and counties for which the data (mortality rate from drug overdoses or drug overdose death numbers) required to demonstrate eligibility for grants is not available.

Finally, the section requires the Comptroller General to conduct a study to determine whether the data being used to assess local areas' eligibility for formula grant funding provide the most precise measure of local areas' need for such funding, or whether additional data would provide more precise measures of substance use and addiction prevalence.

SECTION 3401(c):
This section stipulates that grants shall be awarded to the chief elected official of the eligible local area receiving the funds. In the case of multiple contiguous counties submitting one application for funds, this section stipulates that grant funds will be administered by the chief elected official of the county identified in the application submitted by the group of counties. This section also allows multiple contiguous counties to elect to have the state administer their grant funds if they prefer.

SECTION 3402(a):
This section requires eligible local areas to establish a substance use disorder services planning council in order to receive grant funds. This section requires the membership of these planning councils to include (to the maximum extent possible): representatives of health care providers (including federal qualified health centers, rural health clinics, Indian health programs, Native Hawaiian organizations, and facilities operated by the Department of Veterans Affairs); community-based health, harm reduction, or addiction service organizations, including representatives of Drug Free Communities Coalition grantees; social service providers; mental health care providers; local public health agencies; law enforcement officials; affected communities (including individuals with substance use disorder or a history of substance use disorder); State and local governments (including the State Medicaid agency and the Single State Agency for Substance Abuse Services); non-elected community leaders; substance use disorder providers; members of Federally-recognized Indian tribes; former prisoners; organizations that provide services to youth at risk of substance abuse; labor unions and the workplace community;

fire departments and emergency medical services; and historically underserved groups and sub-populations.

SECTION 3402(b):
This section clarifies that the council may be created for the purposes of this grant program, or an existing entity with demonstrated experience in the provision of health and support services to individuals with substance use disorder may be designated to serve as the council.

This section also directs the Secretary to establish a process permitting eligible local areas that are not contiguous with any other eligible local areas to form a joint planning council with other eligible local areas as long as such areas are located in geographical proximity to each other (as determined by the Secretary) and submit a joint application.

Finally, the section allows eligible local areas to form a joint planning council with other eligible local areas located across State lines if such areas are in geographical proximity and if they establish an intergovernmental agreement to allow the administration of a grant across State lines.

SECTION 3402(c):
This section specifies that members of the planning council shall be nominated and selected through an open process and shall elect from within their membership a chair and vice chair.

This section also specifies that a planning council must include at least one representative from Indian tribes located within any eligible local area.

Finally, the section prohibits an individual from serving more than three consecutive years on a planning council, except that individuals may serve additional terms if they are nominated and selected through the open process through which all planning council members are selected.

SECTION 3402(d):
This section specifies that the planning council shall establish priorities for the allocation of grant funds within the local area that emphasize reducing drug overdose and substance use disorder through evidence-based interventions in both community and criminal justice settings. The section specifies that these priorities shall be based on the use by the grantee of evidence-based treatment and intervention strategies that comply with best practices identified by the Secretary, the cost-effectiveness of the proposed interventions, the priorities of the communities and individuals within the local area that are affected by substance use, and the availability of other governmental and non-governmental services.

This section also requires planning councils to ensure that grant funds are expended consistent with any existing state or local plan regarding the provision of substance use disorder treatments.

The section also requires that in the absence of a state or local plan, the planning council must work with local public health agencies to develop a comprehensive plan for the organization and delivery of substance use disorder treatment services.

The section also requires the planning council to assess the efficiency of the administrative mechanism in allocating these funds, and to work with local public health agencies to determine the size, demographics, and needs of the population of individuals with substance use disorder; determine disparities in access to services among affected subpopulations and historically underserved communities; establish methods for obtaining input on community needs and priorities; and coordinate with Federal grantees providing substance use-related services in the area.

The section also requires local planning councils to annually assess the effectiveness of the treatments and services support by grants, including: reductions in the rates of death from substance use disorder, rates of discontinuance of treatment among individuals receiving treatment, long-term outcomes among individuals receiving treatment, and the availability of treatment and support services needed by individuals with substance use disorder over their lifetimes.

SECTION 3402(e):
This section sets forth protections against conflicts of interest in planning councils, stating that the planning council itself may not be directly involved in the administration of a grant. This section also stipulates that if a planning council member has a financial interest in an entity, this individual may not participate in the process of selecting entities to be grant recipients.

SECTION 3402(f):
This section requires planning councils to establish procedures for addressing grievances related to funding.

SECTION 3402(g):
This section requires planning council meetings to be open to the public, requires detailed minutes to be kept, and requires records and minutes to be made publicly available. This section exempts personal information, including personal medical information, from these public disclosure requirements.

SECTION 3403(a):
This section states that the Secretary shall make a grant to each local area whose application under section 3404 is approved. This section also outlines the manner in which grant funds shall be calculated and distributed.

This section requires the Secretary to distribute 53 percent of the funds appropriated under this subtitle for grants to local areas through formula grants. Each local area receives funding equal to 53 percent of total local area appropriations, multiplied by each local area's share of total drug overdose deaths for all eligible local areas. However, this section also allows the number of non-fatal overdoses to be used to determine a local area's share of funding if that factor results in a higher distribution than would be provided using total drug overdose deaths.

This section defines drug overdose deaths to be the number of drug overdose deaths during the most recent three-year period for which data are available. The section allows non-fatal drug overdose numbers to be calculated on the basis of data such as emergency department syndromic

data, visits, or other emergency medical services for drug-related causes during the most recent three-year period for which such data are available.

This section also directs the Comptroller General to conduct a study to determine whether the data used in this funding formula "provide the most precise measure of local area need related to substance use disorder and addiction prevalence in local areas and whether additional data would provide more precise measures of substance use and addiction prevalence in local areas." The Comptroller General is also directed to make recommendations for revising the distribution factors used in this section in order to direct funds to the local areas most in need of funding.

This section provides funding for local areas that are eligible for formula funding in one year but then lose eligibility in a subsequent year. Such local areas would be eligible for 80 percent of their previous funding during the first year of lost eligibility and 50 percent of previous funding during the second subsequent year.

This section reserves the remaining 47 percent of funds appropriated for local areas to be disbursed through competitive grants to local areas that submit applications to the Secretary. This section stipulates that applications for competitive grants shall contain a report about the use of the formula grants, demonstrate need on an objective and quantified basis for supplemental funding, demonstrate the existing commitment of resources to combating substance use disorder, demonstrate the ability of the area to effectively utilize supplemental financial resources, demonstrate that resources will be allocated in accordance with local demographic incidence of substance use disorder and drug overdose mortality, demonstrate consistency of proposed services with local needs assessment and statewide coordinated statement of need, demonstrate success in identifying individuals with substance use disorder, and demonstrate that support for substance use disorder treatment services is organized to maximize the value to the population to be served with an appropriate mix of treatment services and attention to transition in care.

This section further requires that in determining the size of these competitive grants, the Secretary shall consider the rate of drug overdose deaths and the increasing need for substance use disorder treatment services, including the relative rates of increase in overdoses, or recent increases not reflected in the data used to determine formula grant funding.

This section states that in determining a local area's need for funding, the Secretary may include factors such as the unmet need for services, relative rates of increase in the number of drug overdoses or drug overdose deaths within new or emerging subpopulations, the prevalence of substance use disorders, the cost and complexity of delivering services to individuals in the local area, the impact of co-morbid factors, the prevalence of homelessness among individuals with substance use disorders, other factors that limit access to health care, the impact of a decline in formula grant funding on services available, and the increasing incidence in conditions related to substance use, including the prevalence of HIV, Hepatitis B and C, and other infections associated with injection drug use.

This section also specifies that local areas receiving only competitive grant funding shall not have to establish local planning councils or meet the eligibility requirements identified for local areas qualifying for formula funding.

SECTION 3403(b):
This section states that eligible local areas receiving only competitive grant funding but not formula funding shall not be required to establish a planning council under section 3402.

This section also establishes that funds provided under this grant may be expended only for: prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, financial assistance with health insurance, and administrative expenses.

This section requires local areas to use grant funds to provide direct financial assistance to eligible entities for the purpose of providing prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses.

This section further clarifies that direct financial assistance may be provided to public or nonprofit private entities, and to private for-profit entities if such entities are the only available provider of quality substance use disorder treatment services in the area.

This section defines "prevention services" as services, programs, or multi-sector strategies to prevent substance use disorder, such as evidence-based education campaigns, community-based prevention programs, opioid diversion, and services to at-risk populations. Local areas are limited to using no more than 20 percent of their total grant funding for prevention services, but are allowed to apply to the Secretary for a waiver of this limit.

This section defines "core medical services" as evidence-based services provided to individuals with a substance use disorder or at risk for developing a substance use disorder, including: stabilization services, withdrawal management and detoxification; intensive inpatient or outpatient treatment; medication assisted treatment; outpatient treatment; residential recovery treatment; outpatient and ambulatory health services; hospice services; mental health services; naloxone procurement, distribution, and training; pharmaceutical assistance and diagnostic testing related to the management of substance use disorders and co-morbid conditions; home and community based services; comprehensive case management; and health insurance enrollment and cost-sharing assistance.

This section defines "recovery and support services" as services, subject to the approval of the Secretary, provided to individuals with substance use disorder, including residential recovery treatment and housing, long term recovery services, 24/7 hotline crisis center support, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services provided while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal, and child and family services.

This section defines "early intervention and engagement services" as services to provide rapid access to substance use disorder treatment as well as counseling and referrals to individuals who have misused substances, who have experienced an overdose, or who are at risk of developing

substance use disorder. It also includes the provision of referrals to facilitate the access of such individuals to core medical services or recovery and support services. The section specifies that the entities through which services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible areas, federally-qualified health centers, and rural health clinics.

This section defines "harm reduction services" as evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

This section specifies that a local area may use grant funds to establish a program of financial assistance to assist individuals with substance use disorder in enrolling in health insurance coverage or affording health care services, including paying cost-sharing amounts.

This section requires participating entities to be Medicaid providers by stating that the Secretary may not make a grant available to a local area unless any services that are available pursuant to the State's Medicaid plan are: A) provided directly by the political subdivision, and the political subdivision has a valid participation agreement under the State's Medicaid plan and is qualified to receive payments under this plan; or B) the political subdivision will enter into an agreement with a public or non-profit private entity under which the entity will provide the service and the entity has entered into such a participation agreement and is qualified to receive such payments.

This section further specifies that these requirements may be waived if the entity providing health care services does not impose a charge or accept third-party reimbursement for its services. It clarifies that determinations of waiver eligibility shall be made without regard to whether the entity accepts donations for the purposes of serving the public.

This section limits a local area to using no more than 10 percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data sharing.

This section specifies that funds received by eligible local areas may be used to provide substance use disorder treatment services to currently incarcerated individuals.

SECTION 3403(b):
This section specifies that 10 percent of the funds available to provide formula grants shall be provided to Indian tribes disproportionately affected by substance use, in an amount determined pursuant to a formula and eligibility criteria developed in consultation with the Indian tribes.

This section specifies that Indian tribes may use the grant funding they receive for the purposes for which any of the grant funding provided under this Section may be used, and for any other activities deemed appropriate by the Secretary in consultation with the tribes.

SECTION 3404(a):
This section specifies that a local area must prepare and submit an application for a grant in such form—and containing such information—as the Secretary may require, including: an accounting of the use of prior grants and results achieved by these grants; a comprehensive plan for the use of the grant funds developed by the planning council; information on the number of individuals to be served by the funds; key outcomes to be measured by grantees; a demonstration that grant funds will be allocated in accordance with the local demographic incidence of substance use; a demonstration that the area will use funds to provide treatment compliant with evidence-based standards, including medication assisted-treatments; a demonstration that past funds were expended in accordance with priorities established by the planning council; a demonstration that the confidentiality of individuals receiving treatment will be maintained; a demonstration that at least one representative from any Indian tribes located in the eligible local area is included in the membership of a planning council; and an explanation of how income, asset, and medical expense criteria will be established and applied.

SECTION 3404(b):
This section requires that an area's application must include various types of maintenance of effort assurances. Specifically, the local area must ensure that funds utilized under the grant will be used to supplement rather than supplant other State or local funds, that the political subdivisions within the local area will maintain a level of expenditures for substance use-disorder treatment services equal to the level of such expenditures in the preceding fiscal year, and that the political subdivisions will not use grant funds to meet this maintenance of effort requirement.

This section also requires that substance use disorder treatment services provided with grant funds be made available without regard to ability to pay for such services or to current or past health conditions.

This section further requires that services be provided in a setting accessible to low-income individuals with substance use disorder and to individuals in rural areas, and that a program of outreach be provided to these individuals.

This section also establishes that grant funds provided to local areas shall be used to make payments for any item or service only if payment cannot be made, or cannot reasonably be expected to be made, under any other State or Federal compensation or health benefits program or any insurance policy, except for programs administered by or providing services to the Indian Health Service.

SECTION 3404(c):
This section specifies that the Secretary may not make a grant to a local area unless the local area provides assurances that individuals with income below 138 percent of poverty will not be charged for services funded by the grant. In the case of individuals with income above 138 percent of poverty, providers will impose charges according to a public schedule.

This section also sets limits on charges for individuals with incomes between 138 percent and 200 percent of poverty (no more than 5 percent of income), individuals with incomes between

200 percent and 300 percent of poverty (no more than 7 percent of income), and individuals above 300 percent of poverty (no more than 15 percent of income).

This section provides that charges may not be imposed for substance use disorder treatment services provided through a grant to any eligible American Indian or Alaska Native individuals.

This section also allows providers to impose only a nominal charge and directs local areas to take into account the total medical expenses of individuals in assessing the amounts charged. The section also requires the local area to agree that the limitation on charges will apply to a specific list of charges, including enrollment fees, premiums, deductibles, cost-sharing, co-payments, co-insurance, and any other charges.

This section also specifies that any requirements imposed on applications from Indian tribes be developed in consultation with the tribes.

SECTION 3405:
This section requires the Secretary to provide technical assistance to newly eligible local areas in the establishment of planning councils and to assist entities in complying with the requirements of this subtitle. This section also authorizes the Secretary to make planning grants available to eligible areas, in amounts not to exceed $75,000, which shall be subtracted from the first year's formula award to such areas.

SECTION 3406:
This section authorizes ten years of appropriations for these grant programs, totaling $27 billion.

SUBTITLE B (Grants to States)

SECTION 3411:
This section establishes a grant program, administered by the Secretary of Health and Human Services in coordination with the Director of the Office of National Drug Control Policy, to be awarded to States, territories, and tribal governments for the purpose of addressing substance use.

SECTION 3412(a):
This section requires the Secretary to disburse 50 percent of the amount appropriated under section 3415 to States within 90 days after an appropriation becomes available and establishes the formula used to distribute these funds. This section states that each State, the District of Columbia, and the territory of Puerto Rico will receive the greater of a minimum allotment of $2 million or an amount determined through a specified formula. Other territories will receive a minimum allotment of $500,000.

This section lays out the formula used to determine funding for States. Each State receives funding equal to the total appropriation available for formula grants multiplied by each State's share of total drug overdose deaths. However, this section also weights this distribution factor toward States that have more deaths occurring outside local areas that are already eligible for local-area grants under Section 3401. This section requires the Secretary to determine the

overall appropriations going to a State or territory on the basis of the higher of either the number of fatal drug overdoses or the number of non-fatal drug overdoses.

This section defines drug overdose deaths to be the number of drug overdose deaths during the most recent three-year period for which data are available. The section allows non-fatal drug overdose numbers to be calculated on the basis of data such as emergency department syndromic data, visits, or other emergency medical services for drug-related causes during the most recent three-year period for which such data are available.

This section also directs the Comptroller General to conduct a study to determine whether the data used for in this funding formula "provide the most precise measure of State need related to substance use and addiction prevalence and whether additional data would provide more precise measures of the levels of substance use and addiction prevalence in local areas." The Comptroller General is also directed to make recommendations for revising the distribution factors used in this section in order to direct funds to the States most in need of funding.

This section reserves the remaining 50 percent of funds appropriated for States to be disbursed as competitive grants to States that submit an application to the Secretary. This section stipulates that this application shall contain a report about the use of the formula grants, demonstrate need on an objective and quantified basis for supplemental funding, demonstrate the existing commitment of resources to combating substance use disorder, demonstrate the State's ability to effectively utilize supplemental financial resources, demonstrate that resources will be allocated in accordance with demographic incidence of substance use disorder and drug-related mortality, demonstrate consistency of proposed services with a State's needs assessment and statewide coordinated statement of need, demonstrate success in identifying individuals with substance use disorder, and demonstrate that support for substance use disorder treatment services are organized to maximize the value to the population to be served with an appropriate mix of substance use disorder treatment services and attention to transition in care.

This section further requires that in determining the size of these competitive grants, the Secretary shall consider the rate of drug overdose deaths and the increasing need for substance use disorder treatment services, including the relative rates of increase in overdoses, or recent increases not reflected in the data used to determine formula grant funding.

This section states that in determining a State's need for funding, the Secretary may include factors such as the unmet need for services; relative rates of increase in the number of drug overdoses or overdose deaths; the prevalence of substance use disorders, the cost and complexity of delivering services to individuals in the State; the impact of co-morbid factors, the prevalence of homelessness; other factors that limit access to health care, the impact of a decline in formula grant funding on services available; and increases in the incidence of conditions related to substance abuse, including HIV, Hepatitis B and C, and other infections associated with injection drug use.

This section also requires the Secretary to give preference in awarding competitive grants to States that have adopted the model standards developed in accordance with section 3434. However, beginning in 2025, any State that has not adopted the model standards developed in

accordance with section 3434 will not be eligible to receive a grant through the competitive process.

This section specifies that 10 percent of the funds available to provide formula grants shall be provided to Indian tribes, in an amount determined pursuant to a formula and eligibility criteria developed in consultation with the Indian tribes. This section specifies that Indian tribes may use the grant funding they receive for the purposes for which any of the grant funding provided under this Section may be used, and for any other activities deemed appropriate by the Secretary in consultation with the tribes.

SECTION 3412(b):
This section requires States to use grant funds to provide prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses.

This section defines "prevention services" as services or programs to prevent substance use disorder, such as evidence-based education campaigns, community-based prevention programs, opioid diversion, and services to at-risk populations (including children at risk for substance use disorder or residing in homes with individuals with substance use disorders, currently or formerly incarcerated individuals, individuals with mental illness, and homeless individuals). States are limited to using no more than 20 percent of their total grant funding for prevention services, but are allowed to apply to the Secretary for a waiver of this limit.

This section defines "core medical services" as evidence-based services provided to individuals with a substance use disorder or at risk for developing a substance use disorder, including: stabilization services, withdrawal management and detoxification; intensive inpatient or outpatient treatment; medication assisted treatment; outpatient treatment; residential recovery treatment; outpatient and ambulatory health services; hospice services; mental health services; naloxone procurement, distribution, and training; pharmaceutical assistance and diagnostic testing related to the management of substance use disorders and co-morbid conditions; home and community based services; comprehensive case management; and health insurance enrollment and cost-sharing assistance.

This section defines "recovery and support services" as services, subject to the approval of the Secretary, provided to individuals with substance use disorder, including residential recovery treatment and housing, long term recovery services, 24/7 hotline crisis center support, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services provided while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal, and child and family services.

This section defines "early intervention and engagement services" as services to provide rapid access to substance use disorder treatment as well as counseling and referrals to individuals who have misused substances, who have experienced an overdose, or who are at risk of developing substance use disorder. It also includes the provision of referrals to facilitate the access of such

individuals to core medical services or recovery and support services. The section specifies that the entities through which services may be provided include emergency rooms, fire departments, and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible areas, federally-qualified health centers, and rural health clinics.

This section defines "harm reduction services" as evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

This section specifies that a State may use grant funds to establish a program of financial assistance to assist individuals with substance use disorder in enrolling in health insurance coverage or affording health care services, including paying cost-sharing amounts.

This section limits a State to using no more than 10 percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data sharing.

This section specifies that funds received by states may be used to provide substance use disorder treatment services to currently incarcerated individuals.

SECTION 3413(a):
This section specifies that a State must prepare and submit an application for a grant in such form—and containing such information—as the Secretary may require, including: an accounting of the use of prior grants and results achieved by these grants; a comprehensive plan for the use of the grant funds that is consistent with local needs; information on the number of individuals to be served by the funds; key outcomes to be measured by grantees; a demonstration that grant funds will be allocated in accordance with the local demographic incidence of substance use; a demonstration that the State will use funds to provide treatment compliant with evidence-based standards, including all federally approved medication assisted-treatments; a demonstration that past funds were expended in accordance with State priorities; a demonstration that the confidentiality of individuals receiving treatment will be maintained; and an explanation of how income, asset, and medical expense criteria will be established and applied.

SECTION 3413(b):
This section requires that a State's application must include various types of maintenance of effort assurances. Specifically, the State must ensure that funds utilized under the grant will be used to supplement rather than supplant other State or local funds, that the political subdivisions within the State will maintain a level of expenditures for substance use disorder treatment services equal to the level of such expenditures in the preceding fiscal year, and that the political subdivisions will not use grant funds to meet this maintenance of effort requirement.

This section also requires that substance use disorder care and support services provided with grant funds be made available without regard to ability to pay or current or past health conditions. This section further requires that services be provided in a setting accessible to low-

income individuals with substance use disorder and individuals in rural areas, and that a program of outreach be provided to these individuals.

This section also establishes that grant funds provided to local areas shall be used to make payments for any item or service only if payment cannot be made, or cannot reasonably be expected to be made, under any other State or Federal compensation or health benefits program or any insurance policy, except for programs administered by or providing services to the Indian Health Service.

SECTION 3413(c):
This section states that in order for a State to be eligible for a grant under this subtitle, the State must have in effect a Medicaid IMD waiver or have submitted an application for such a waiver.

SECTION 3413(d):
This section specifies that the Secretary may not make a grant to a State unless the State provides assurances that individuals with income below 138 percent of poverty will not be charged for services funded by the grant. In the case of individuals with income above 138 percent of poverty, providers will impose charges according to a public schedule. This section also sets limits on charges for individuals with incomes between 138 percent and 200 percent of poverty (no more than 5 percent of income), individuals with incomes between 200 percent and 300 percent of poverty (no more than 7 percent of income), and individuals above 300 percent of poverty (no more than 15 percent of income).

This section provides that charges may not be imposed for substance use disorder treatment services provided through a grant to any eligible American Indian or Alaska Native individuals.

This section also allows providers to impose only a nominal charge and directs States to take into account the total medical expenses of individuals in assessing the amounts to be charged. The section also requires the State to agree that the limitation on charges will apply to a specific list of charges, including enrollment fees, premiums, deductibles, cost-sharing, co-payments, co-insurance, and any other charges.

SECTION 3413(e)
This section states that a State will not be eligible to receive a grant unless the State develops and publishes a statewide coordinated statement of need, including a demonstration of the extent of State need for assistance in addressing addiction and substance use disorder in the State and identifying priorities for the delivery of essential services to individuals with substance use disorder and their families.

SECTION 3413(f)
This section specifies that any requirements imposed on applications from Indian tribes be developed in consultation with the tribes.

SECTION 3414:

This section requires the Secretary to provide technical assistance in administering and coordinating activities authorized under section 3412 and in helping States apply for supplementary grants.

SECTION 3415:
This section authorizes ten years of appropriations for these grant programs, totaling $40 billion.

SUBTITLE C (Grants to Clinics and Nonprofits)

SECTION 3421(a):
This section establishes a grant program administered by the Secretary of Health and Human Services to public, nonprofit, and Native entities for the purpose of funding core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses.

SECTION 3421(b):
This section outlines criteria for eligibility for public, nonprofit, and Native entities. These entities may include: federally-qualified health centers; family planning clinics; rural health clinics, Native entities including Indian health programs, urban Indian organizations, and Native Hawaiian organizations; community-based organizations, clinics, hospitals, and other facilities that provide substance use disorder treatment services; other nonprofit entities providing substance use disorder treatment services, and faith-based organizations providing these services.

This section also specifies that eligible entities shall serve underserved populations, which may include minority and Native American populations; ex-offenders; individuals with comorbidities including HIV/AIDS and Hepatitis B or C; mental illness other behavioral health disorders; low-income populations; inner city populations; and rural populations.

This section also specifies that in order to be eligible to receive a grant, a public or nonprofit entity shall prepare and submit to the Secretary an application for funds in such form, and including such information, as the Secretary shall require, including: an accounting of the use of prior grants and results achieved by these grants; a comprehensive plan for the use of the grant funds; information on the number of individuals to be served by the funds; key outcomes to be measured by grantees; a demonstration that grant funds will be allocated in accordance with the local demographic incidence of substance use; a demonstration that the entity will use funds to provide treatment compliant with evidence-based standards; including medication assisted-treatments; a demonstration that the confidentiality of individuals receiving treatment will be maintained; and an explanation of how income, asset, and medical expense criteria will be established and applied.

SECTION 3421(c):
This section requires participating entities to be Medicaid providers by stating that the Secretary may not make a grant available to a local area unless any services that are available pursuant to the State's Medicaid plan are: A) provided directly by the political subdivision, and the political subdivision has a valid participation agreement under the State's Medicaid plan and is qualified to receive payments under this plan; or B) the political subdivision will enter into an agreement

with a public or non-profit private entity under which the entity will provide the service and the entity has entered into such a participation agreement and is qualified to receive such payments.

This section further specifies that these requirements may be waived if the entity providing health care services does not impose a charge or accept third-party reimbursement for its services. It clarifies that determinations of waiver eligibility shall be made without regard to whether the entity accepts donations for the purposes of serving the public.

SECTION 3421(d)
This section specifies that 10 percent of the grant funds shall be used to provide grants to Native entities in amounts determined pursuant to criteria developed by the Secretary in consultation with Indian tribes.

This section also specifies that Native entities may use grant amounts for the purposes for which any grant under Section 3422 may be used as well as any other activities deemed appropriate by the Secretary in consultation with the Indian tribes.

SECTION 3422(a):
This section states that an eligible entity may use these grants to provide prevention services, core medical services, recovery and support services, early intervention and engagement services, harm reduction services, and administrative expenses.

SECTION 3422(b):
This section defines "prevention services" as services or programs to prevent substance use disorder, such as evidence-based education campaigns, community-based prevention programs, opioid diversion, and services to at-risk populations (including children at risk for substance use disorder or residing in homes with individuals with substance use disorders, currently or formerly incarcerated individuals, individuals with mental illness, and homeless individuals). Local areas are limited to using no more than 20 percent of their total grant funding for prevention services, but are allowed to apply to the Secretary for a waiver of this limit.

SECTION 3422(c):
This section defines "core medical services" as evidence-based services provided to individuals with a substance use disorder or at risk for developing a substance use disorder, including: stabilization services, withdrawal management and detoxification; intensive inpatient or outpatient treatment; medication assisted treatment; outpatient treatment; residential recovery treatment; outpatient and ambulatory health services; hospice services; mental health services; naloxone procurement, distribution, and training; pharmaceutical assistance and diagnostic testing related to the management of substance use disorders and co-morbid conditions; home and community based services; comprehensive case management; and health insurance enrollment and cost-sharing assistance.

SECTION 3422(d):
This section defines "recovery and support services" as services, subject to the approval of the Secretary, provided to individuals with substance use disorder, including residential recovery treatment and housing, long term recovery services, 24/7 hotline crisis center support, medical

transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services provided while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal, and child and family services.

SECTION 3422(e):
This section defines "early intervention and engagement services" as services to provide rapid access to substance use disorder treatment as well as counseling and referrals to individuals who have misused substances, who have experienced an overdose, or who are at risk of developing substance use disorder. It also includes the provision of referrals to facilitate the access of such individuals to core medical services or recovery and support services.

The section specifies that the entities through which services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible areas, federally-qualified health centers, and rural health clinics.

SECTION 3422(f):
This section defines "harm reduction services" as evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

SECTION 3422(g):
This section limits an eligible entity to using no more than 10 percent of its total grant for administration, accounting, reporting, and program oversight, including for the purposes of developing systems to improve data collection and data sharing.

SECTION 3423:
This section authorizes the Secretary to provide technical assistance to nonprofit private entities regarding the process of submitting grants and may provide technical assistance with respect to the planning, development, and operation of any program or service.

SECTION 3424:
This section authorizes the Secretary to provide planning grants to public, nonprofit private entities, and Native entities for purposes of assisting such entities in expanding their capacity to provide evidence-based substance-use related health and support services in low-income communities and underserved populations. Grants made available under this section shall not exceed $150,000.

SECTION 3425:
This section authorizes ten years of appropriations for these grant programs, totaling $5 billion.

SUBTITLE D (Special Projects of National Significance)

SECTION 3431(a):

This section specifies that the Secretary, acting in consultation with the Director of the Office of National Drug Control Policy, shall award grants to entities to administer special projects of national significance to support the development of innovative and original models for the delivery of substance use disorder treatment services.

SECTION 3431(b):
This section specifies that the Secretary shall award grants under this section to entities eligible for grants under subtitles A (local areas), B (States), and C (nonprofits and clinics) based on newly emerging needs of individuals receiving assistance under this title.

SECTION 3431(c):
This section specifies that the Secretary shall make information regarding successful models or programs developed under this section available to grantees in order to facilitate coordination, replication, and integration. This section also authorizes the Secretary to provide for peer-based technical assistance for grantees funded under this section.

SECTION 3431(d):
This section requires the Secretary to use 10 percent of the funding made available for special projects of national significance to provide grants to Indian tribes for the purposes of supporting the development of innovative and original models for the delivery of substance use treatment services, including the development of culturally-informed care models.

SECTION 3431(e)
This section authorizes ten years of appropriations for these grant programs, totaling $5 billion.

SECTION 3432: (Education and Training Centers)
This section authorizes the Secretary to make grants and enter into contracts to assist public and nonprofit private entities, schools, and academic medical centers in meeting the costs of projects to train health personnel (including counselors, case managers, social workers, peer recovery coaches, and harm reduction workers) in the diagnosis, treatment, and prevention of substance use disorders, including measures for the prevention and treatment of co-occurring infectious diseases and other conditions and care for women, pregnant women, and children.

This section allows the use of funds to train the faculty of schools of medicine and other health professions to teach students to screen for and provide for the needs of individuals with substance use disorder or at risk of substance use disorder and to develop and disseminate curricula and resource materials related to the screening, prevention, and treatment of substance use disorder, including information about prescribing best practices, alternative pain therapies, and medication-assisted treatment.

This section states that in making such grants, the Secretary shall give preference to qualified projects that will train or result in the training of health professionals who will provide services for underserved groups, minority health professionals and minority-allied health professionals, individuals who will provide treatment in rural or other areas underserved by current treatment structures, and professionals who will provide treatment for infectious diseases and mental health conditions co-occurring with substance use disorder.

This section requires the Secretary to use 10 percent of the amounts made available for education and training centers to provide grants to tribal colleges and universities, Indian Health Service grant funded institutions, and Native partner institutions, including institutions of higher education with medical training programs that partner with one or more Indian tribes, tribal organizations, native Hawaiian organizations, or tribal colleges and universities to train Native health professionals who will provide substance use disorder treatment services in Native communities.

This section authorizes ten years of appropriations for these grant programs, totaling $5 billion.

SECTION 3433:
This section requires that recipients of grant funding under this title that offer substance use disorder treatment services agree to offer all FDA-approved forms of medication-assisted substance use disorder treatment for the substance use disorders for which the applicant offers treatment. This section also allows applicants to receive a waiver to this requirement if they provide a justification and agree to require all entities offering substance use disorder treatment services under the grant to offer at least two Federally-approved forms of medication-assisted treatment on site, counsel patients on the benefits and risks of all forms of Federally-approved medication-assisted treatments, and maintain an affiliation with a provider that can prescribe or otherwise dispense all other forms of Federally-approved medication-assisted treatment.

This section also requires the Comptroller General to conduct a study describing any relationship between substance use rates, pain management practices of the Indian Health Service, and patient request denials through the purchased or referred care program of the Indian Health Service.

SECTION 3434(a):
This section requires the Secretary, in consultation with the American Society of Addiction Medicine, to promulgate model standards for the regulation of substance use disorder treatment services.

SECTION 3434(b):
This section specifies that the model standards shall: identify the type of providers covered and shall not include a private practitioner who is already licensed by a State medical licensing board and whose practice is limited to outpatient care; require that all substance use disorder treatment services be licensed by States; identify the professional credentials needed by each type of substance use disorder treatment professional; require that patients have access to licensed substance use disorder treatment services for inpatient and outpatient care; identify and develop strategies for States to ensure that all substance use disorder patients receive a medical assessment; require States to implement a process to ensure that residential treatment provider qualifications are verified by the single State agency regulating such services or by an independent third party with the necessary competencies to use evidenced-based patient placement assessment tools and nationally-recognized program standards, as applicable; ensure that patients receiving treatment for substance use disorder have access directly, or by referral or in such other manner as the Secretary determines, to FDA-approved medication assisted treatment; develop standards for data reporting; develop standards for licensed providers to

ensure that patients receive an outpatient treatment and discharge plan; and require the designation of a single State agency to serve as the primary regulator in the State for substance use disorder programs.

This section also requires regulations to develop standards for the certification of recovery residences. Such standards must include: application, inspection, and renewal procedures; fire, safety, and health standards; standards for equipping such residences with naloxone and training residence owners, operators, and employees in the administration of naloxone; standards for recovery residence owners and operators; and standards to identify, disqualify from grant funding, and refer to the appropriate regulatory authority, any entity engaged in patient brokering. Standards developed by the Secretary must also require States to establish a toll-free complaint line related to recovery residences and establish and maintain a publicly accessible online list of all certified recovery residences in the State.

This section also requires the model standards developed by the Secretary to require the single State agency regulating substance use disorder treatment services to ensure that treatment provider assessments for all substance use disorder treatment services, including levels of care and length-of-stay recommendations, are verified by an independent third party that has the necessary competencies to use evidenced-based patient placement assessment tools and nationally-recognized program standards, as applicable.

This section also requires the model standards developed by the Secretary to require States to consider existing barriers to substance use disorder treatment service access, including capacity and infrastructure needs, as well as access to culturally attuned services.

SECTION 3434(c):
This section requires the Secretary, beginning in 2021, to make an annual determination with respect to each State on whether the State has adopted the model regulations promulgated in accordance with this section.

SECTION 3434(d):
This section also directs the Secretary to engage a non-profit, non-partisan standards development and quality measurement organization to convene regulators, States, consumer representatives, treatment providers, recovery residence owners and operators, and purchasers of substance use disorder treatments to develop and annually revise a set of health care quality measures to substance use disorder treatment providers and owners and operators of recovery residences.

SECTION 3435(a):
This section requires the Secretary to provide for the purchase and delivery of Federally-approved opioid overdose reversal products on behalf of each State and Indian tribe that receives funding under subtitle B. This section establishes budget authority in the amount of $500 million annually in advance of appropriations Acts.

In the event that sufficient overdose reversal drug products are not available, this section directs the Secretary to give preference to States with at least one local area eligible to receive a formula grant for local areas under Section 3401.

SECTION 3435(b):
This section requires the Secretary to negotiate with manufacturers of opioid overdose reversal products and to consolidate such contracting with other contracting activities conducted by the Secretary. This section also authorizes the Secretary to decline to enter into contracts or modify or extend contracts as necessary.

The section provides that the price for these drug products shall be a discounted price negotiated by the Secretary.

This section provides that all opioid overdose reversal products purchased under this contract shall contain, for each dose, the maximum amount of active opioid antagonist recommended by the Food and Drug Administration as an initial dose and a minimum of two doses packaged together.

This section requires the Secretary to provide for the purchase and delivery of these products on behalf of States and tribal organizations and allows each State and Indian tribe to obtain additional quantities of opioid overdose reversal products at the same discounted price.

This section also requires the Secretary to enter into initial negotiations not later than 180 days after the enactment of this title.

This section authorizes the Secretary to enter into a contract with a drug manufacturer only if the manufacturer agrees to submit such reports as the Secretary deems necessary to ensure compliance with the contract and if the manufacturer agrees not to impose additional delivery costs.

This section also allows the Secretary to enter into contracts with multiple manufacturers, provided each manufacturer meets the terms and conditions of the contract, and allows States to choose which contract will be applicable to their purchase of additional quantities of overdose reversal products.

This section requires that beginning not later than one year after the Secretary enters into the first contract under this Section, the Secretary shall use a list established by an advisory committee established by the Secretary and located within the Centers for Disease Control and Prevention (CDC) which considers the cost-effectiveness of each overdose reversal product as the basis for the purchase, delivery, and administration of these products.

This section requires States to distribute opioid overdose reversal products received under this section to first responders and to public entities with the authority to administer local public health services. These public entities are directed to make products available to public and nonprofit entities (including rural health clinics, community-based organizations, non-profit

entities and faith-based organizations providing treatment or harm reduction services) and the general public.

In order to be eligible to receive opioid overdose reversal drugs under this section, each State shall establish a program for distributing these products to first responders and local health departments, demonstrate a distribution rate of a minimum of 90 percent of the opioid overdose reversal products received under this program, and certify to the Secretary that the State has in place measures that enhance access to opioid overdose reversal products.

This section also requires the Indian Health Service, in consultation with Indian tribes, to determine any requirements that shall apply to Indian tribes receiving opioid overdose reversal products through the program established by this section.

This section contains definitions related to the opioid overdose reversal product negotiation program.

SECTION 3436:
This section authorizes ten years of appropriations, totaling $10 billion, to the National Institutes of Health for the purposes of conducting research on addiction and pain related to substance misuse.

SECTION 3437:
This section authorizes ten years of appropriations, totaling $5 billion, to the CDC for the purposes of improving data on drug overdose deaths and non-fatal drug overdoses, surveillance related to addiction and substance use disorder, and the prevention of transmission of infectious diseases related to substance use.

This section requires the CDC to use a portion of the funding appropriated under this section to ensure all States participate in the Enhanced State Opioid Overdose Surveillance program and to provide technical assistance to medical examiners and coroners to facilitate improved data collection.

This section requires that not less than 1.5 percent of the funding made available to the CDC be provided to Indian tribe epidemiology centers.

SECTION 3438:
This section provides applicable definitions for this title.

SECTION 4 (AMENDMENTS TO CONTROLLED SUBSTANCES ACT)

This section identifies the types of companies—distributors, dispensers, and manufacturers—covered by these amendments to the Controlled Substances Act. Covered persons are those entities that distribute, manufacture, or dispense a schedule II controlled substance and are required to register under section 302(a)(1) or 302(a)(2) of the Controlled Substances Act.

This section also defines covered officers as the president, CEO, chief medical officer, and chief counsel of a covered entity. This section exempts officers of opioid treatment providers dispensing medication-assisted treatment from the requirements of this section.

This section requires that, not later than 180 days after the enactment of this section and each year thereafter, each covered officer of a covered person submit to the Attorney General, for each schedule II controlled substance, a signed certification that the covered entity maintains effective controls against diversion of the controlled substance into channels other than legitimate medical, scientific, research, or industrial channels, verifying the accuracy of information contained in any record, inventory, or report required to be kept or submitted to the Attorney General by the covered person under section 307, or under any regulation issued under that section, and attesting that the company is in compliance with all applicable requirements under Federal law to report suspicious orders for controlled substances. Covered officers of covered manufacturers must also submit a signed certification that the controlled substance is not misbranded, as defined in section 502 of the Food, Drug, and Cosmetic Act.

This section establishes that it shall be unlawful to fail to submit these certifications. This section also states that it shall be unlawful for any covered officer of a covered person to submit a certification—without regard to the state of mind of the covered officer—that contains a materially false statement or representation relating to the controls against diversion or the misbranding of the controlled substance.

Covered officers are subject to civil penalties of a fine of not more than $25,000 if they submit a false certification. If covered officers willfully submit a false certification, they can be subject to criminal penalties specified under section 403(d) of the Controlled Substances Act of not more than four years imprisonment.

This section also establishes a "Comprehensive Addiction Resources Emergency Fund" and directs 100 percent of any civil penalty or criminal fine paid to the federal government under this section to the fund and dedicates the fund to the grants established by this Act.

Finally, this section also amends the Controlled Substances Act by including the text of S. 2317, the bipartisan Addiction Treatment Access Improvement Act of 2018, which codifies a 2016 regulation to increase the number of patients that qualified physicians may treat with buprenorphine from 100 to 275. This language also makes permanent a pilot program established in the Comprehensive Addiction and Recovery Act to allow certain non-physician qualified health practitioners to prescribe buprenorphine.